

CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 **DOVER, DELAWARE 19904-2467**

STATE OF DELAWARE BOARD OF PHARMACY TELEPHONE: (302) 744-4500 FAX: (302) 739-2711

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PUBLIC MEETING NOTICE: **BOARD OF PHARMACY**

DATE AND TIME: Wednesday, September 17, 2014 9:30 am

Conference Room A, 2nd Floor Cannon Building PLACE:

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: October 15, 2014

MEMBERS PRESENT

Kenneth Sellers, Public Member, President Susan Esposito, R.Ph, Professional Member, Vice President Kimberly Robbins, R.Ph, Professional Member Bonnie Wallner, R.Ph, Professional Member Jay Galloway, Public Member David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

Joli Martini, R.Ph., PharmD, Professional Member Tejal Patel, R.Ph, PharmD, Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III

ALSO PRESENT

Don Holst Leon Rapuano III Jon Reitz Caitlin Benenati Judee Olimbo Michael D McAleu Marissa Siok **Noel Rosas**

Ann Campagna Nicholas Petrovich

Sean Reilly Jaime Frink

Elena Mason

Ashley Tillman

Darrall Heaton Nancy Sawyer

Tiffany Sorey Deb Hamilton Kevin Musto Haley Kavelak

CALL TO ORDER

Mr. Sellers called the meeting to order at 9:34 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Esposito, seconded by Mr. Galloway, to approve the meeting minutes as amended for August 20, 2014. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Sellers read a letter of resignation provided to the board from Ms. Sandra Zaragoza. Ms. Zaragoza cited personal reasons for her resignation and thanked the board for allowing her to serve. Mr. Sellers publicly thanked Ms. Zaragoza for her service and request a letter of service be drafted and sent to her. Mr. Dryden will draft the letter. Mr. Sellers having nothing else to report continued to the next agenda item.

UNFINISHED BUSINESS

Complaint Status

- 13-03-11 Assigned to Hearing Officer
- 13-09-11 Assigned to Hearing Officer
- 13-12-11 Forwarded to Office of Attorney General
- 13-19-11 Forwarded to Office of Attorney General
- 13-09-12 Assigned
- 13-01-13 Forwarded to Office of Attorney General
- 13-02-13 Assigned
- 13-03-13 Assigned
- 13-04-13 Forwarded to Office of Attorney General
- 13-05-13 Assigned
- 13-06-13 Forwarded to Office of Attorney General
- 13-07-13 Assigned
- 13-08-13 Assigned
- 13-09-13 Assigned
- 13-11-13 Forwarded to Office of Attorney General
- 13-13-13 Forwarded to Office of Attorney General
- 13-14-13 Assigned
- 13-15-13 Assigned
- 13-16-13 Assigned
- 13-17-13 Assigned
- 13-18-13 Assigned
- 13-19-13 Assigned
- 13-20-13 Assigned
- 13-21-13 Assigned
- 13-22-13 Assigned
- 13-23-13 Assigned
- 13-24-13 Assigned

Re-Review of Consent Agreement

None

Proposal to Deny Hearing

Harshadrai P Patel: scheduled for 9:45 am. No show for hearing. A motion was made by Ms. Robbins, seconded by Ms. Esposito to final deny the application. The motion carried unanimously.

Concierge Compounding Pharmacy, scheduled for 10:00 am provided a letter requesting the hearing to be rescheduled.

Re-Review of Tabled Applications

None

Review of Practitioner/Pharmacy Ownership

Mr. Dryden stated that health care stakeholders have been solicited for feedback regarding this issue. Ms. Wallner asked if the statute provide a definition of a "practitioner". Mr. Dryden responded that there is a clear and definitive definition within the pharmacy statute.

24 Del. C. §2512 Issuance and Renewal of Licensure Review

Mr. Dryden reported that an alert was sent regarding HB154 w/HA2 of the Delaware code related those who register to prescribe, sell, dispense or distribute controlled substances demonstrate regularly to complete 2 continuing education credits in the area of awareness and knowledge of the problems posed by the abuse of controlled substances. This will be removed from the agenda as satisfied.

Re-Review of CPR Course - Emergency University, Ca.

During discussion the board consensus included the importance of hands on training and certification. Mr. Galloway will conduct more research and report back to the board during the next scheduled meeting. A motion was made by Ms. Robbins, seconded by Ms. Wallner, to table the request for more information. The motion unanimously carried.

Review of DEA Federal Rules for Disposal

Mr. Dryden reported that the DEA has passed Federal Rules for drug disposal. The Board was provided a handout of the rules provided from the DEA website. Mr. Dryden stated that the pharmacy board may need to review changes to the rules and regulations to provide an authorizing statement for the DEA Federal Disposal statute. The DEA has asked Mr. Dryden to attend a national meeting being held on September 30th through October 1, 2014. Mr. Dryden asked the board to review the new DEA Federal Disposal statute and that this agenda item remain as an ongoing item for the purpose of updating the board.

NEW BUSINESS

Mr. Sellers read into the record the following ratifications. Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0004652 Ryan Michael Fillis

A1-0004653 Annmarie R. Tiangco

A1-0004654 Hey Sun Um

A1-0004655 Yun K. Hong

A1-0004656 Lauren Marie Navarre

A1-0004657 Miranda R. O'Brien

A1-0004658 Joseph L. Guan

A1-0004659 Francis Joseph Chin

A1-0004660 Maritza Sanchez

A1-0004661 Danny T. Yang

A1-0004662 Brian P. Pizzano

A1-0004663 Phyllis D. Rasmussen

A1-0004664 Merlin Tchawa Yimga

A1-0004665 David D. Kim

A1-0004666 Yongmu Huang

A1-0004667 So Jung Lee

A1-0004668 Zhiyong Lu

A1-0004669 Stephen H. Karcsh

A1-0004670 Stephen M. Maylie

A1-0004671 Denise S. Olusala
A1-0004672 Monisha Mathews
A1-0004673 Shilpa Mohan
A1-0004674 Tiffany O. Russell
A1-0004675 Priyankkumar J. Patel
A1-0004676 Kyle Wilcox
A1-0004677 Jane Ann Nouhra
A1-0004678 Andree Marie Dargin
A1-0004679 Jeenha Park
A1-0004680 Kellen O. Riley
A1-0004681 Amir E. Yacoub
A1-0004682 Zein elabdeen Elbagir Eissa
A1-0004683 Michelle Campbell
A1-0004684 Masato C. Sugeno
A1-0004685 Yasmin N. Kyeremateng

A motion was made by Ms. Esposito, seconded by Ms. Wallner to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002375 Alicia R. Vickers A7-0002376 Matthew R. Mullins

A motion was made by Ms. Esposito, seconded by Ms. Wallner to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001489 CareSite Specialty Rx A9-0001490 Lehigh Pharmacy & Supplies, Inc. A9-0001491 Jack P. Herick Inc, DBA Glades Drugs A9-0001492 Gentry Health Services, Inc. A9-0001494 Praxis Rx Pharmacy A9-0001495 LIfe-Q, LLC A9-0001496 SunQuest Pharmaceuticals Inc. A9-0001497 Peterson Rx, LLC A9-0001498 Medical Arts Pharmacy Services Inc. A9-0001499 Alicea Enterprises, LLC A9-0001500 Injured Workers Pharmacy, LLC A9-0001501 Injured Workers Pharmacy, LLC A9-0001502 Central Rexall Drugs, Inc A9-0001503 Pharmaceutical Specialties Express A9-0001504 Athena Pharmacy A9-0001505 Northmark Pharmacy

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001795	Premium Rx National, LLC
A4-0002114	Areva Pharmaceuticals Inc
A4-0002115	Kadmon Pharmaceuticals, LLC
A4-0002116	Walgreens Specialty Pharmacy #15443
A4-0002118	McKesson Medical-Surgical, Inc.
A4-0002119	McKesson Medical-Surgical Inc.

A4-0002120 Philips Healthcare

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

None

Retail Pharmacy Licensure Approval Ratification

None

Pharmacist-In-Charge Interviews

Ms. Robbins conducted a PIC interviews with:

Sean Reilly, CVS - New Castle, DE

Darrall Heaton, Health South - Middletown, DE

A motion was made by Ms. Esposito, seconded by Ms. Wallner to amend the agenda to add the following R.Ph. for PIC interview. The motion unanimously carried.

Marisa Siok, Walgreens – Dover, DE Noel Rosas, Walgreens – Bridgeville, DE Nicholas Petrovich, Walgreens – Harrington, DE Elena Mason, CVS – Dover, DE Caitlin Benenati, CVS – Bear, DE Ashley Tillman. CVS – Newark, DE

Consultant Pharmacist Interviews

None

Board Review and Consideration of Consent Agreement

Leonard Bronstein: a motion was made by Mr. Galloway and seconded by Ms. Wallner, to reject the consent agreement as presented. The motion unanimously carried.

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the board ruling:

Facility: Coast Quality Pharmacy a motion was made by Ms. Esposito, seconded by Ms. Robbins, to approve the application. The motion unanimously carried.

Facility: KV Vet Supply a motion was made by Ms. Wallner, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: McKesson Medical Surgical a motion was made by Ms. Esposito, seconded by Mr. Galloway, to table the application. The motion unanimously carried.

Facility: Walgreen Pharmacy Services-Midwest a motion was made by Mr. Galloway, seconded by Ms. Wallner, to propose to deny the application. The motion unanimously carried.

Facility: Exact Care Pharmacy a motion was made by Ms. Robbins, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: Genoa Healthcare a motion was made by Mr. Galloway, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

CE Approval Requests

None

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

No Report

Continuing Education — Joli Martini, Bonnie Wallner, and David Dryden:

No Report

Consumer Affairs - Ken Sellers and Jay Galloway:

No Report

Professional Liaisons - Kim Robbins:

No Report

Controlled Substance Liaisons – Joli Martini, Jay Galloway and David Dryden:

Mr. Dryden reported that delegate accounts for the PMP were launched. September 27, 2014 is the DEA National Drug take back date.

COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Dryden reported that the board is ready to move forward with previously discussed proposed regulations changes. Ms. Kelly has draft rules and regulations prepared. The next step is to schedule public hearings as required by statute.

Pharmacy Technician Licensure Committee – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Sandy Esposito and David Dryden:

Mr. Dryden provided detailed information regarding current pharmacy statute, and rules-regulations that could assist with the boards' concerns of unlicensed pharmacy technicians. This would provide a means to address the concerns of the board and may not require licensure of technicians. This will remain as an agenda item for ongoing discussion.

Collaborative Care Committee — Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

Ms. Miro-Wenger reported that a meeting was held a little over 2 weeks ago. The committee decided on a couple of additional paths to move forward. The committee has held several calls with retail and hospital pharmacy members for their feedback. The committee is currently reviewing lowa and Michigan legislation to assist in preparing draft legislation to be presented this fall. The committee is hopeful in providing the board with a copy of the draft at its next scheduled meeting.

BOARD CORRESPONDENCE

None

<u>EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim</u>

Mr. Dryden reported that the Division of Professional Regulation assisted with an investigation in conjunction with the Delaware State Police, and Alcohol & Tobacco Enforcement. The investigation resulted in several unlicensed practice charges as well as criminal charges.

Mr. Dryden also reported that an FDA Alert was received regarding NuVision. Mr. Dryden contacted the FDA as well as the New York, Board of Pharmacy. NuVision did have sterility issues related to drugs. However, none of the drugs were distributed.

The Medical Society has almost completed the continuing education 1 credit hour per 3.0 of the Rules and Regulations of the Controlled Substance Act for all practitioners. Mr. Dryden will be reviewing the content in the near future.

Mr. Dryden provided a copy 16 Del. C. 4739(a) regarding the 72 hour dispensing statute. This statute has caused related issues to our Veterinary Practitioners as well as Methadone clinics within the state. Amendments have been prepared to be presented in the near future to exclude Veterinarians and Methadone clinics.

NEWSLETTER UPDATES

None

OTHER BUSINESS BEFORE THE BOARD

Ms. Mast requested the board to provide clarity on 24 Del. C. 2512(e) regarding the maximum allowable years a pharmacist can be inactive over the lifetime of licensure. Ms. Kelly, the board DAG, will research the statute and report back during the next scheduled meeting.

PUBLIC COMMENT

Mr. Musto stated that during the last Delaware Pharmacists Society (DPS) meeting there were discussions surrounding the Executive Director vacancy, ways to Celebrate Pharmacy month, and upcoming DPS events. Mr. Musto asked that the following dates be noted: October 10, 2014 – APHA Centered Diabetic Training will be held, October 11, 2014 DPS Diabetic Conference, and May 11-13, 2015 the DPS Convention in Dewey Beach Delaware.

Mr. Phil Anderson, on behalf of Walgreens and other colleagues, wished to take the opportunity to thank Christine Mast for expeditiously licensing many pharmacy graduates this graduation season. Mr. Anderson stated that Delaware is among the top of the states to provide support and licensure in a timely manner and should be recognized as such. Ms. Mast recognized the entire team of support staff in accomplishing this task.

NEXT SCHEDULED MEETING

The next meeting is scheduled for October 15, 2014 at 9:30 am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the board the meeting adjourned at 12:04 pm.

Respectfully submitted,

Christine Mast

Administrative Specialist III